

Regulation of prices and reimbursement of medicinal products

Abstract

Medicinal products are essentially part of every human life. It is therefore desirable to ensure that they are offered on the market at a fair and affordable price, precisely through price and reimbursement regulation. The aim of this diploma thesis is to analyse how the regulation of prices and reimbursements applies to human medicinal products in the provision of outpatient health care, the price and reimbursement of which is decided by the State Institute for Drug Control in administrative proceedings. In order to achieve this goal, the thesis is divided into four parts.

The first part defines the basic concepts needed to understand the meaning and purpose of the system of price and reimbursement regulation, such as a medicinal product, price or reimbursement. Furthermore, this part is devoted to the types of administrative acts occurring in the field of price and reimbursement regulation and introduces the Ministry of Health and the State Institute for Drug Control as the most important administrative authorities operating in this field. The second part analyses the legislation effective until 31st December 2007. The forms of administrative activity then performed by the Ministry of Health and the Ministry of Finance are analysed in more detail, using the knowledge of administrative acts from the first part. The second part also analyses the impact of European Union law in this field, in particular the Transparency Directive, the key judgement of the Constitutional Court, which repealed the effective regulation of reimbursement regulation at that time, and the Act on the Stabilization of Public Budgets, which introduced a completely new system of pricing and reimbursement. The third and fourth part of this thesis is focused on the current legal regulation of the process of pricing and reimbursement of medicinal products in administrative proceedings, as well as their changes or cancellation. These parts also deal with issues of participation in these administrative proceedings, the locus standi of the parties to judicial review, or the issue of providing free healthcare.

Key words:

price, reimbursement, regulation, medicinal product, public health insurance